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- (54) Title of the Invention: Strip for Tooth Bleaching
- (57) Abstract

[Problem] To provide a strip for tooth bleaching which is easy to handle and can stick exactly to the specific tooth surface so that, in application to the tooth, there is no contamination from running of the bleaching agent onto the gingiva and/or inside the oral cavity.

[Solution] A strip for tooth bleaching constructed with 1 ~ 3 layers prepared with pullulan film or synthetic resin film as a protective film on one or both surfaces of a pullulan film containing a bleaching agent such as hydrogen peroxide, urea peroxide, carbamide peroxide, or sodium peroxyborate.

#### Claims

Claim 1. A strip for tooth bleaching which is a pullulan film containing a bleaching agent as a bleaching material for cosmetic whitening of the teeth.

Claim 2. A strip for tooth bleaching whereby a barrier-like synthetic resin film layer is arranged on one side of a pullulan film containing a bleaching agent.

Claim 3. A strip for tooth bleaching whereby pullulan film is layered on one or both surfaces of a pullulan film containing a bleaching agent.

Claim 4. The strip for tooth bleaching of any of Claims  $1 \sim 3$  whereby the thickness of any layer of the respective layers is  $10 \,\mu \sim 40 \,\mu$ .

Claim 5. The strip for tooth bleaching of any of Claims 1 ~ 4 whereby the bleaching agent which is contained on pullulan is chosen from hydrogen peroxide, urea peroxide, carbamide peroxide, or sodium peroxyborate.

Claim 6. The strip for tooth bleaching of any of Claims 1 ~ 5 whereby the protective barrier-like synthetic resin film is a film chosen from PE, polyurethane, nylon-6, or nylon-66.

[Detailed Description of the Invention]

[0001]

[The Technical Range of the Invention] The invention concerns a bleaching strip for whitening teeth. Also, the invention concerns a safe bleaching strip whereby, while whitening the discoloration of teeth due to food and drink, tobacco, bacteria, etc., a sheet is used which serves as a barrier to the bleaching agent so that bleaching agent does not adhere to the gingiva and/or the inside of the oral cavity apart from the teeth. [0002]

#### [Prior Art]

In prior art, as a whitening technology to remove stains discoloring the teeth due to food and drink, tobacco, bacteria, etc., Kokai H06-128130 gives notice of a known liquid polymer compound which whitens teeth. The liquid polymer compound used for this contains an oxidant and hydro-alcohol in a water soluble cellulose polymer and, when applied to the teeth, a film is formed by the evaporation of solvent but the film continually releases oxidant; so it is unreasonable to apply the liquid polymer compound which whitens teeth at home before sleeping, as during the time after application until the solvent evaporates the mouth must remain open, and it is difficult to peel off the film which forms from the teeth. Thus, in prior art the search for a material to whiten teeth which removes stains discoloring teeth, generally at home, easily, and at any time, is not fulfilled with this.

[0003]

Also, Kokai H10-017448 proposes a two-layer sheet consisting of a support layer and an adhesive layer combining whitening ingredients such as kojic acid, kojic acid, kojic acid derivatives on the adhesive layer which sticks to the tooth surface. By using a high molecular substance non-soluble in water for an ingredient of the support layer and water soluble high molecular substance for an ingredient of the adhesive layer, it attaches to the tooth when the adhesive layer is moistened with water. The support layer is a cellulose-type sheet. Ethyl cellulose, cellulose acetate group polymers, (meta-) acrylic acid group polymers, polyvinyl acetal group polymers, etc. can be used for the water soluble high molecular substance, but there is an unpleasant feeling with these polymers as a barrier is not provided for the chemical being

used for whitening the teeth and during use the chemical scatters and sticks to the gingiva and/or the inside of the oral cavity. Kojic acid type whitening ingredients are mixed with the adhesive layer and, as it is placed in an open manner, the 2-layer structure invites a decline in effectiveness and degeneration of the active ingredient.

#### [0004]

US patents, 5,879,691 and 5,891,453, are also 2-layered structures in which a gel containing the whitening agent is applied to a flexible support sheet; this is equipped with concave pockets by embossing to hold the gel onto the support sheet. The sheet on which the gel is applied is difficult to handle because the gel sticks to the fingers, gets dirty, and becomes gooey in handling and, as the support sheet does not provide a barrier to the bleaching agent, there is the problem of the active substance sticking or scattering on the gingiva and inside the oral cavity.

#### [0005]

[Problems the Invention Is To Solve] An excellent whitening sheet with a view towards maintaining uniform effectiveness requires a sheet providing a barrier for the chemical ingredient contained on the sheet and preferably a barrier for the chemical ingredient on the surface adhering to the teeth so that there is no contamination of the gingiva or the inside of the oral cavity. Such a strip for bleaching is not yet known. The present invention solves these problems by proposing a strip for tooth bleaching which does not get dirty or gooey in handling by the adherence of the active substance gel to the fingers and is easy to handle; further, the supporting sheet is provided with a barrier for the whitening agent so that the active substance does not stick to or scatter on the gingiva and/or inside the oral cavity and there is no unpleasantness arising from such.

#### [0006]

[Means of Solving the Problems] The present invention, as a strip for tooth bleaching, solves the above-mentioned problems by having a base layer of pullulan film containing the bleaching agent and, suitably, a layered product of 1 ~ 3 layers providing a pullulan film or synthetic resin film on one or both sides of said base layer.

#### [0007]

To be more precise, the present invention has the following construction:

- (1) A strip for tooth bleaching which is a pullulan film containing a bleaching agent as a bleaching material for esthetic whitening of the teeth.
- (2) A strip for tooth bleaching whereby a barrier-like synthetic resin film layer is arranged on one side of a pullulan film containing a bleaching agent.
- (3) A strip for tooth bleaching whereby pullulan film is layered on one or both surfaces of a pullulan film containing a bleaching agent.
- (4) The strip for tooth bleaching of any of Claims  $1 \sim 3$  whereby the thickness of any layer of the respective layers is  $10 \,\mu \sim 40 \,\mu$ .

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- (5) The strip for tooth bleaching of any of Claims 1 ~ 4 whereby the bleaching agent which is contained on pullulan is chosen from hydrogen peroxide, urea peroxide, carbamide peroxide, or sodium peroxyborate.
- (6) The strip for tooth bleaching of any of Claims 1 ~ 5 whereby the protective barrier-like synthetic resin film is a film chosen from PE, polyurethane, nylon-6, or nylon-66.

  [0008]

In the strip for tooth bleaching of the present invention, the suitability and improvement of a barrier for the bleaching agent is appropriate and, when observing the air permeability (CC/m²24hr.atm) of various kinds of films - for example, it is 1.3 CC/m²24hr.atm for pullulan, 50 CC/m²24hr.atm for nylon, 200 CC/m²24hr.atm for PET, 500 CC/m²24hr.atm for PE, and 1,100 CC/m²24hr.atm for PE - for the present invention a barrier of pullulan film is the most applicable. Also, in the present invention there is no use of an ingredient in a gel state; because the active ingredient constructed on the respective film layer is in a dry state, it is easy to handle and can be applied accurately to a specific tooth surface. When applying to the tooth there is no contamination from running of the bleaching agent onto the gingiva and/or inside the oral cavity. Therefore it is a safe product with which there is no unpleasant feeling or stimulation.

Since the pullulan body itself adheres to the tooth by the moisture of the tooth, there is no need to use a gel type fastening ingredient in the present invention. For example, in the case of preparing a protector of pullulan film or synthetic resin film, there is a film layer which includes pullulan containing bleaching agent under that film layer and, as there is no system of opening, there is no change of concentration of hydrogen peroxide of the like and the ingredient's effectiveness can be stabilized. The construction of the present invention is such that there is a  $1 \sim 3$  layer structure using pullulan in a base and, at the least, in the base there exists a pullulan film containing the bleaching agent; suitably, a protective pullulan film or synthetic resin film is arranged on one or both sides of said base and the respective thickness of each layer is preferably  $10 \mu - 40 \mu$ . If it is less than  $10 \mu$ , handling is inconvenient. If it is more than  $40 \mu$ , a three-layer structure would be  $120 \mu$ , the film would be uncomfortable for the oral cavity, and thus unsuitable for use.

[0010]

For the bleaching agent which is to be contained in the pullulan film of the strip for tooth bleaching of the present invention, one can choose among hydrogen peroxide, urea peroxide, carbamide peroxide, or sodium peroxyborate. The concentration of said bleaching agent can be in the range of  $1 \sim 10$  % by weight and  $2 \sim 7$  % by weight is particularly appropriate. If the concentration of bleaching agent contained in pullulan is less than 1% by weight, a whitening effect is not obtained. Concentrations more than 10% by weight cannot be used because they are harmful and injurious to the tissues of the oral cavity. When using the strip for tooth bleaching of the present invention, it is indispensable that there is a pullulan film as a layer in contact with the tooth; because the pulluan dissolves by the saliva attached to the tooth, the bleaching agent for whitening contained on the base layer is activated and the tooth surface becomes whitened.

[0011]

The present invention is described in more detail with working examples but the construction of the present invention is not influenced by the construction of the working examples.

[0012]

[Working Example 1] On a 20  $\mu$  pullulan film containing 4% by weight of hydrogen peroxide and 0.1% by weight of sodium citrate, a film consisting of 100% pullulan 40  $\mu$  thick is piled up so as to make 2 layers; after stamping out a strip formed to adhere to a tooth, a strip for tooth bleaching is obtained. The strip obtained was adhered to the tooth for 30 min. and then rinsed out well with water. This operation was carried out once a day for 14 consecutive days. After 14 days, the cosmetic whitening of the tooth was verified. During the testing there were no unpleasant feeling or tissue abnormalities inside the oral cavity. [0013]

[Working Example 2] A 20  $\mu$  pullulan film containing 5% by weight of urea peroxide and 0.2% by weight of sodium citrate is layered between a film consisting of 100% pullulan 20  $\mu$  thick and a PE film 20  $\mu$  so as to make 3 layers; after stamping out a strip formed to adhere to a tooth, a strip for tooth bleaching is obtained. The strip obtained was adhered to the tooth for 30 min. and then rinsed out well with water. This operation was carried out once each day for 14 consecutive days. After 14 days, the whitened appearance of the tooth was verified. During the testing there were no unpleasant feeling or tissue abnormalities inside the oral cavity.

[0014]

[Working Example 3] A 20  $\mu$  pullulan film containing 4% by weight of carbamide peroxide and 0.1% by weight of sodium citrate is layered between a film consisting of 100% pullulan 20  $\mu$  thick and a polyurethane film 20  $\mu$  so as to make 3 layers; after stamping out a strip formed to adhere to a tooth, a strip for tooth bleaching is obtained. The strip obtained was adhered to the tooth for 30 min. and then rinsed out well with water. This operation was carried out once each day for 14 days in a row. After 14 days, the whitened appearance of the tooth was verified. During the testing there were no unpleasant feeling or tissue abnormalities inside the oral cavity.

[0015]

[Effect of the Invention] With the strip for tooth bleaching of the present invention, since the pullulan body adheres to the tooth by the moisture of the tooth, there is no need to use a gel type fastening for the contact ingredient, there is a pullulan layer containing bleaching agent under that pullulan layer and, as there is no kind of opening, there is no change of concentration of hydrogen peroxide or the like, and the ingredient's effectiveness can be stabilized. In addition, the strip for tooth bleaching of the present invention, not using a gel state, has a pullulan layer containing the bleaching agent, is always a sheet in a dry state, easy to handle, and able to be applied exactly to a specific tooth surface. Also, in application to the tooth, there is no contamination from bleeding of the bleaching agent on the gingiva and/or inside the oral cavity; for this reason it can be used safely without unpleasant feeling or stimulation.

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